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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/869,334	09/26/2001	Hirofumi Endo	P21289	5711

7055 7590 03/31/2005

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EXAMINER

RAMIREZ, DELIA M

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 03/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/869,334

Applicant(s)

ENDO ET AL

Examiner

Delia M. Ramirez

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 January 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) 1-13 and 16-20 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 14, 21-24 and 38 is/are allowed.
- 6) ☒ Claim(s) 15, 25-36, 39 is/are rejected.
- 7) ☒ Claim(s) 37 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 1/14/05.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Claims 1-39 are pending.

Applicant's amendment of claims 15, 25-37, 39 in a communication filed on 1/14/2005 is acknowledged.

This application contains claims 1-13 and 16-20 drawn to an invention non-elected with traverse in a communication filed on 5/13/2004. A complete reply to the final rejection must include cancellation of non-elected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01. Claims 14-15 and 21-39 are under consideration and are being examined herein.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Information Disclosure Statement

1. The information disclosure statement (IDS) submitted on 1/14/2005 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Specification

2. The abstract of the specification is objected to as it contains legal phraseology. See, for example, the term "said". Appropriate correction is required.

Claim Rejections - 35 USC § 112, Second Paragraph

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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4. Claims 15, 25-36 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection as it relates to claim 15 is necessitated by amendment.

5. Claim 15 is indefinite in the recitation of “about 99% homology” for the following reasons. The term “about” can be interpreted as “less than” and/or “more than”. Since neither the specification nor the claim has defined “about 99% homology”, one would not be reasonably apprised of the scope of the invention. In addition, the term “homology” is found indefinite since one cannot determine if Applicant’s intended meaning of the term is “identity” and the term has not been defined in the specification. As known in the art, sequence identity and sequence homology are not equivalent terms. The calculation of sequence homology takes into consideration the type of mismatches, i.e. even mismatches contribute to the % homology value, whereas mismatches do not have any weight in the calculation of sequence identity, i.e. only exact matches contribute to the % identity value. For examination purposes, it will be assumed that the term reads “at least 99% identity”. Correction is required.

6. Claims 25-28 (claims 29-36 dependent thereon) remain indefinite due to the recitation of “treated product of the culture”. Applicants argue that based on the teachings of the specification, one of skill in the art would understand that the term includes dried cells, lyophilized cells, cells treated with surfactants, cells treated with enzymes, cells treated with ultrasonication, cells treated with mechanical milling, cells treated with solvents, protein fractions of the cells, or immobilized product of cells. This argument is not found persuasive. While it is agreed that the specification exemplifies what could be considered a “treated product of the culture”, the specification does not define the term as encompassing only what has been exemplified. As such, the term may encompass other items in addition to what has been exemplified which cannot be determined in view of the fact that one of skill in the art cannot establish the scope of the term “treated”. It is suggested that claims 25-28 be amended to include the limitations of claim 37 as they relate to the term “treated product of the culture”. If the suggested amendment is made,

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claim 37 would have to be canceled. As previously indicated, for examination purposes, it will be assumed that the term reads “any fraction of the culture”. Correction is required.

Claim Rejections - 35 USC § 112, First Paragraph

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claim 15 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection necessitated by amendment.

Claim 15 is now directed (as interpreted) to a DNA encoding a polypeptide consisting of an amino acid sequence having at least 99% sequence identity with the amino acid sequence of SEQ ID NO: 1, and having the ability of producing the recited compounds from the recited substrates. While Applicants assert that support for this amendment is found in the specification as it discloses SEQ ID NO: 1, 2, 41 and 42, as well as in the fact that SEQ ID NO: 42 is 99.7% homologous to SEQ ID NO: 1, this argument is not found persuasive. The Examiner acknowledges Applicant's assertion regarding the degree of homology between SEQ ID NO: 1 and 42, and agrees that there is support for SEQ ID NO: 1, 2, 41 and 42. However, it is noted that the asserted level of homology between SEQ ID NO: 1 and SEQ ID NO: 42 does not provide support for an entire genus of DNAs encoding a polypeptide consisting of an amino acid sequence having at least 99% sequence identity with the amino acid sequence of SEQ ID NO: 1. There is no indication in the specification that in addition to a polynucleotide encoding the polypeptide

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of SEQ ID NO: 42, a preferred embodiment of the invention is the entire genus of DNAs encoding a polypeptide having at least 99% sequence identity to SEQ ID NO: 1. Thus, there is no indication that such genus was within the scope of the invention as conceived by Applicants at the time the application was filed. Accordingly, Applicants are required to cancel the new matter in response to this Office Action.

9. Claims 25-36 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection has been discussed at length in the Non Final Action mailed on 7/14/2005.

10. Applicants argue that it would be clear to a skilled person in the art that the treated products of the culture include dried cells, lyophilized cells, cells treated with surfactants, cells treated with enzymes, cells treated with ultrasonication, cells treated with mechanical milling, cells treated with solvents, protein fractions of the cells, or immobilized product of cells. Furthermore, Applicants submit that these products may be used as an enzyme source for the claimed method.

11. As indicated previously, this rejection was applied in view of the interpretation of the claims as it relates to the term "treated product of the culture" (i.e. "any fraction of the culture"). Applicant's arguments have been fully considered but are not deemed persuasive to overcome the rejection in view of the fact that the claims still recite the term "treated product of the culture". Since the claims have been interpreted as directed to process for producing the recited compounds with any fraction of the culture, including one which lacks the enzyme, this rejection is maintained for the reasons of record.

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12. It is noted that this rejection may be overcome by amending claims 25-28 to include the limitations of claim 37 in regard to what is encompassed by the term “treated product of the culture”. If the suggested amendment is made, claim 37 would have to be canceled.

13. Claims 25-36 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a process for producing the specific compounds recited with (a) the polypeptide of SEQ ID NO: 1, or (b) a fraction of a culture containing the polypeptide of SEQ ID NO: 1, does not reasonably provide enablement for a process for producing the specific compounds recited with a fraction of a culture which does not comprise the polypeptide of SEQ ID NO: 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. This rejection has been discussed at length in the Non Final Action mailed on 7/14/2005.

14. Applicants argue that it would be clear to a skilled person in the art that the treated products of the culture include dried cells, lyophilized cells, cells treated with surfactants, cells treated with enzymes, cells treated with ultrasonication, cells treated with mechanical milling, cells treated with solvents, protein fractions of the cells, or immobilized product of cells. Furthermore, Applicants submit that these products may be used as an enzyme source for the claimed method.

15. As indicated previously, this rejection was applied in view of the interpretation of the claims as it relates to the term “treated product of the culture” (i.e. “any fraction of the culture”). Applicant’s arguments have been fully considered but are not deemed persuasive to overcome the rejection in view of the fact that the claims still recite the term “treated product of the culture”. Since the claims have been interpreted as directed to process for producing the recited compounds with any fraction of the culture, including one which lacks the enzyme, this rejection is maintained for the reasons of record.

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16. It is noted that this rejection may be overcome by amending claims 25-28 to include the limitations of claim 37 in regard to what is encompassed by the term "treated product of the culture". If the suggested amendment is made, claim 37 would have to be canceled.

Claim Rejections - 35 USC § 102

17. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

18. Claim 15 remains rejected under 35 U.S.C. 102(b) as being anticipated by Rivolta et al. (Microbiology 144:877-884, 1998; cited in the IDS; GenEMBL accession number AF015825, May 1998). This rejection has been discussed at length in the Non Final Action mailed on 7/14/2005.

19. Applicants argue that while Rivolta et al. discloses the yjiB gene from B. subtilis, the polynucleotide complementary to SEQ ID NO: 2 was not made nor there is direction to make this complementary polynucleotide in the document. Furthermore, Applicants submit that Rivolta et al. only discloses a predicted function of a presumed ORF and does not disclose an isolated yjiB gene or an isolated DNA encoding a polypeptide consisting of an amino acid having about 99% homology with the amino acid sequence of SEQ ID NO: 1 and having an activity of producing compound (II-a) or compound (II-b) from compounds (I-a) or (I-b).

20. Applicant's arguments have been fully considered but are not deemed persuasive to overcome the instant rejection. Rivolta et al. teaches an isolated DNA which encodes a polypeptide which is 100% sequence identical to the polypeptide of SEQ ID NO: 1. The polypeptide of Rivolta et al. is exactly the same size as that of SEQ ID NO: 1 (396 amino acids). As such, the DNA of Rivolta et al. is an isolated DNA encoding a polypeptide which is at least 99% sequence identical to SEQ ID NO: 1, which is the subject matter of amended claim 15 as interpreted. The Examiner disagrees with Applicant's contention that Rivolta et al. does not teach an isolated yjiB gene in view of the fact that the gene of Rivolta et al.

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had to be isolated to be sequenced. Rivolta et al. clearly teaches that the yjiB gene was sequenced (page 878; Cloning and sequencing). Therefore, the teachings of Rivolta et al. anticipate the instant claim as written.

Claim Rejections - 35 USC § 103

21. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

22. Claim 39 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Rivolta et al. (Microbiology 144:877-884, 1998; cited in the IDS; GenEMBL accession number AF015825, May 1998). This rejection has been discussed at length in the Non Final Action mailed on 7/14/2005.

23. Applicants argue that while Rivolta et al. discloses the yjiB gene from *B. subtilis*, the polynucleotide complementary to SEQ ID NO: 2 was not made nor there is direction to make this complementary polynucleotide in the document. Furthermore, Applicants submit that because Rivolta et al. does not teach or suggest an oligonucleotide consisting of 5-60 contiguous nucleotides of SEQ ID NO: 2 or a complete complement of such oligonucleotide, it would not have been obvious to one of ordinary skill in the art at the time the invention was made to make such a probe just from the start codon of the polynucleotide disclosed by Rivolta et al.

24. Applicant's arguments have been fully considered but are not deemed persuasive to overcome the rejection. The Examiner, as previously indicated, acknowledges that the instant reference does not teach an oligonucleotide consisting of 5-60 contiguous nucleotides of SEQ ID NO: 2, however, the teachings of Rivolta et al. render the claimed invention obvious in view of the fact that Rivolta et al. teaches an oligonucleotide comprising the first 3 nucleotides of SEQ ID NO: 2. As indicated previously, one of skill in the art would be motivated to construct such an oligonucleotide for use as a probe. For example, an oligonucleotide comprising 5-60 contiguous nucleotides of the polynucleotide of Rivolta et al. which

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include the start codon of the polynucleotide of Rivolta et al. can be used to detect structurally homologous genes in other species. As previously indicated, the polynucleotide of Rivolta et al. comprises all of SEQ ID NO: 2 with only one mismatch at position 462 of SEQ ID NO: 2. Therefore, the invention as a whole would have been prima facie obvious to one of skill in the art at the time the invention was made.

Allowable Subject Matter

25. Claims 14, 21-24 and 38 appear to be allowable over the prior art of record.
26. Claim 37 appears to be allowable over the prior art of record but it is objected to since it depends upon a rejected base claim.
27. Claims 25-36 appear to be allowable over the prior art of record and it would be allowable if amended to overcome the 35 USC 112, second paragraph rejection and related 35 USC 112, first paragraph rejection as indicated above.

Conclusion

28. Applicant's amendment of claims 15, 25-37, 39 necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

29. Certain papers related to this application may be submitted to Art Unit 1652 by facsimile transmission. The FAX number is (571) 273-8300. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If Applicant submits a paper by FAX, the original copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.


30. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

31. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (571) 272-0938. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (571) 272-0928. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Delia M. Ramirez, Ph.D.
Patent Examiner
Art Unit 1652

DR
March 17, 2005


REBECCA E. PROUTY
PRIMARY EXAMINER
GROUP 1800
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